MICHIGAN PHARMACISTS ASSOCIATION

October 6, 2015

Re: **MPA Letter of Support for HB 4437**

Members of the Health Policy Committee:

On behalf of the Michigan Pharmacists Association I would like to indicate our support for **HB 4437** which will allow for the substitution of lower cost interchangeable biologic products at the point of sale and improve overall access to biosimilar medications. This is similar to how pharmacists today are able to substitute lower cost generic pharmaceuticals at the point of sale, which has led to significant reduction in overall health care and medication spending.

A biologic medication is different from typical medications as they are made using living tissue. This method of manufacturing prohibits companies from making a true generic version of biologic medication as defined by the Federal Food and Drug Administration (FDA). A biosimilar is a biological product that is highly similar to a U.S.-licensed reference biological product notwithstanding minor differences in clinically inactive compounds. Just like traditional brand and generic drugs, **there are no clinically meaningful differences between the approved biosimilar product and the reference biologic product in terms of their safety, purity, and potency.**[i]

The Biologics Price Competition and Innovation Act of 2009 created an abbreviated pathway for FDA to give approval to biologics that are biosimilar to originator products. Additionally, a path was made for the production of products that could be considered to be interchangeable with approved biologic reference products. **HB 4437 refers to these as "interchangeable biologic products," which is consistent with the language already established at the federal level.** The FDA is in the process of establishing standards for proving interchangeability so that these drugs may safely be brought to market.

Increasing access to biologics, biosimilars and interchangeable biologics is critical as **these agents are used to treat a variety of diseases** including cancer, AIDS, psoriasis, heart disease, rheumatoid arthritis, asthma, and multiple sclerosis, among others. Branded biologics, however, are currently quite expensive. **The average daily cost of a brand name biologic product is approximately 22 times greater than a traditional drug.**[ii] Additionally, by 2016 it is predicted that eight of the top ten drugs on the market will be biologics.[iii] Introduction of less expensive alternatives will be vital to curbing rising drug costs.

The FDA is fully cognizant of the complex nature of biologics and has made clear that the standards for determining whether a biologic is interchangeable with an approved reference product will be rigorous. **FDA is the only U.S. regulatory body with the scientific expertise to determine interchangeability**. If FDA approves a biosimilar as interchangeable, the

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interchangeable biosimilar should be substitutable as is the case with generics for branded drug products. States enacting any law that addresses biosimilars would be premature, and even worse, may conflict with the national standards FDA is developing.

Biosimilars have been used in Europe for several years and without any safety issues. Like generic drugs, biosimilars will generally cost less than their branded counterparts. A recent European study determined 8 EU countries could save up to $40.7 billion by 2020 by utilizing biosimilars.[iv] Patients and governments will significantly benefit from the savings generated by interchangeable biosimilars.

Adding any additional administrative hurdles in the substitution and dispensing of interchangeable biologic products will only **increase the burden on prescribers and dispensers, diminish consumer and provider confidence in these new products**, and ultimately **contribute to rising health care costs due to lost efficiency on the part of providers.** HB 4437 is consistent with federal laws that already govern the dispensing of these agents, and fosters an environment in which providers can easily be in compliance with state and federal regulations. We strongly urge your support of this bill.

Sincerely,

Eric Roath, Pharm.D.
Director of Professional Practice
Michigan Pharmacists Association

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[i] FDA definition of a Biosimilar:
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm241718.htm

[ii] Hilary Krame, Why Biologics Remain Expensive, *Forbes* (2009). http://www.forbes.com/2009/12/03/kramer-health-care-intelligent-investing-pharmaceuticals.html

[iii] Statement of John D. Ludwig, Pfizer. http://www.future-science.com/doi/pdf/10.4155/tde.11.58

[iv] http://www.sandoz.com/media_center/news/2012/press_releases/2012_05_18_article.shtml